DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Atlanta District Office
60 8th Street, N.E.
Atlanta, Georgia 30309

December 20, 1996

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. William B. Padgett
7999 Fairmont Highway
Calhoun, Georgia 30701

WARNING LETTER

Dear Mr. Padgett:

An inspection of your operation located in Calhoun, Georgia by a Food and Drug Administration investigator, Marie F. Mathews, on November 29, 1996, confirmed a cow purchased and sold by you on or about July 11, 1996, for slaughter for human food to [redacted] was in violation of Section 402 (a)(2)(D) of the Federal Food, Drug, and Cosmetic Act.

The United States Department of Agriculture (USDA)/ Food Safety and Inspection Service (FSIS) analysis of tissues collected from that animal disclosed the presence of the drug penicillin in the kidney (0.32 ppm) tissue, and (0.14ppm) in the liver muscle. A tolerance of 0.05 ppm has been established for residues of penicillin in the edible tissues of cattle [Title 21 Code of Federal Regulations Section 556.510(a)]. The presence of this drug in edible tissue from this animal causes the food to be adulterated.

In addition, USDA had reported two (2) previous tissue residue violations in samples collected on 4/1/91 and 2/22/94. The 1991 residue was reported as .11 ppm penicillin in the animal's kidney, and the 1994 residue was reported as 4.22 ppm and 2.28 ppm in the liver muscle, and 9.74 ppm oxytetracycline in the animal's kidney (tolerance is 0.10 ppm).

You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice such as seizure and/or injunction.

The violations listed above are not intended to be an all inclusive list. It is your responsibility to assure that your operations are in compliance with the law. As a dealer of animals, you are frequently the individual who introduces or offers for introduction into interstate commerce, the adulterated animal. As such, you share the responsibility for violating the Federal Food, Drug

and Cosmetic Act. To avoid future illegal residue violations you should take precautions such as:

1) implementing a system to identify the animals you purchase with records to establish traceability to the source of the animal;

2) implementing a system to determine from the source of the animal whether the animal has been medicated and with what drug(s); and

3) if the animal has been medicated, implementing a system to withhold the animal from slaughter for an appropriate period of time to deplete potentially hazardous residues of drugs from edible tissue. If you do not want to hold the medicated animal, then it should not be offered for human food, and it should be clearly identified and sold as a medicated animal.

You should be aware that it is not necessary for you to have personally shipped an animal in interstate commerce to be responsible for a violation of the Act. The fact that you offered an animal for sale to a slaughterhouse that ships in interstate commerce is sufficient to hold you responsible for a violation of the Act.

Please advise this office in writing, within fifteen (15) working days of receipt of this letter, of the specific action you have taken or intend to take to bring your operation into compliance with the law, including measures to prevent the recurrence of similar violations. Your response should be directed to Barbara A. Wood, Compliance Officer, at the above address.

Sincerely yours,

for Roger E. Klein
Ballard H. Graham, Director
Atlanta District